

REMARKS

Applicant acknowledges receipt of an Office Action dated August 18, 2009.

Reconsideration of the present application is respectfully requested.

I. Status of the Claims

Claims 5-24, 97, 98-106, 115-121 were withdrawn previously but have been rejoined by the examiner. Claims 94-106, 108-113 and 115-121 are allowed.

Claim 3 is now canceled. Claim 1 is amended to incorporate subject matter from claim 3, which is now canceled without prejudice or disclaimer. Claims 25-93, 107, 114 and 122 were previously canceled. The foregoing amendments are made without prejudice or disclaimer, and do not introduce new matter. Entry and consideration of the amendments is requested. Upon entry of this response, claims 1, 2, 4-24, 94-106, 108-113, and 115-121 will be pending.

II. The Information Disclosure Statement

The examiner refused to consider documents E1-E7, from the Information Disclosure Statement (IDS) filed August 3, 2009. These documents are in Japanese and, in the examiner's view, were not accompanied by a concise explanation of their relevance. Action at page 2. In fact, the August 3rd IDS expressly stated that the English language equivalents has been submitted previously, and the IDS provided the publication or patent numbers of those previously provided documents. By way of further clarification, applicant notes that documents E1, E2, E3, E4, E5 and E6, as listed in the August 3rd IDS, respectively correspond to documents D5, D6, D3, D2, D1 and D7 filed with the IDS of November 10, 2008. E7 is an action by the Japanese Patent Office, citing documents E1-E6, in relation to the Japanese counterpart application.

III. Rejections under the written description provision of 35 U.S.C. § 112, first paragraph, and the accompanying objection of claims 4 and 5.

Claims 1-3 and 6-24 are rejected for allegedly exceeding the written description provided by the specification. Action at pages 2-6. Claims 4 and 5 are objected as depending from a rejected base claim (claims 1 or 2), but the examiner deems them allowable if rewritten in independent form. *Id.* at page 6.

The examiner asserts that the claims exceed the underlying written description because they are not limited with respect to (a) the methylotrophic yeast or (b) the mammalian sugar chain. Action at 5, second full paragraph. Applicant respectfully traverses.

On one hand, claims 4 (reciting *Ogataea minuta*) and claim 5 (reciting *Ogataea minuta* strain IFO 106746) depend from claim 1 but are not subject to this rejection, as such. On the other hand, previous claim 3 also depended from claim 1 but prescribed “the genus *Pichia*, *Hansenula*, *Candida*, or *Ogataea*,” and was rejected. Thus, the examiner is heard to say that claims 1 and 2 would be allowable if qualified by the recitation of *Ogataea minuta*.

Solely to advance prosecution, applicant has amended claim 1 to recite “wherein the methylotrophic yeast belongs to the genus *Pichia* or *Ogataea*.” Applicant respectfully contends that amended claim 1 is allowable.

The genera *Pichia* and *Ogataea* are synonymous, and *Ogataea minuta* was previously *Pichia minuta*. See specification at page 13 and Yamada *et al.*, *Biosci. Biotech. Biochem.*, 58, 1245-57 (1994) (abstract appended), which proposed the genus *Ogataea*, with *Ogataea minuta* as the type species. If a revised claim 1, reciting *Ogataea minuta*, is allowable then a claim 1 amended to recite the synonymous *Pichia minuta* likewise should be allowable.

Against this background, the pending Section 112 question is understood to resolve to whether the written description of *Ogataea minuta* in the specification is sufficient support for the recited *Ogataea/Pichia* genus.

In this regard the examiner cites *In re Gostelli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989), where the written description of two species was deemed inadequate to support a genus recitation in the claims. Action at page 4. Yet, a single working embodiment was found to be sufficient written description for a genus in *Invitrogen Corp. v. Clontech Laboratories, Inc.*, 429 F. 3d 1052 (Fed. Cir. 2005) (copy appended), in part because the particular gene under consideration was homologous across species. *Id* at 1073. The *Invitrogen* decision is highly relevant to the present claims, because similar Asn-linked glycosylation pathways exists in other species within *Pichia/Ogataea*, such as *Pichia pastoris*.

Deletion of *OCHI* in *Pichia pastoris* and the introduction and expression therein of the α -1,2-mannosidase gene permitted the production of mammalian sugar chains, according to the PCT publication of Contreras, WO 02/00856, cited by the examiner in the previous Office Action. The existence of the *YPSI* gene in *Pichia pastoris* is evidenced by Werten and Wolf, *Appl. Environ. Microbiol.* 71: 2310-17 (2005), a copy of which appended. The *MNNI* gene, conferring alpha-1,3-mannosyltransferase activity, is present in *Saccharomyces* but is absent from *Ogataea minuta* (specification at pages 13-14) and likewise from *Pichia pastoris*. See Bretthauer *et al.*, *Biotechnol. Appl. Biochem.* 30: 193-200 (1999), copy attached (see page 195 in the left column, lines 16-19).

The genetic similarities between *Ogataea minuta* and *Pichia pastoris*, *inter alia*, bespeak a homology reminiscent of that prompting the *Invitrogen* decision, discussed above, in favor of the applicant there. By the same token, therefore, the present description of *O. minuta* should be considered adequately supportive of the recited *Ogataea/Pichia* genus. Accordingly, reconsideration and withdrawal of the rejection are requested.

CONCLUSION

The present application is deemed in allowable condition, and an early indication to this effect is requested. Examiner Vogel also is invited to contact the undersigned directly, should she feel that any issue warrants further consideration.

Respectfully submitted,

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